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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,367	01/23/2002	Michael Affolter	112843-029	4325
29174	7590	04/25/2006	EXAMINER	
BELL, BOYD & LLOYD, LLC P. O. BOX 1135 CHICAGO, IL 60690-1165			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,367

Applicant(s)

AFFOLTER ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 7, 8, 14-18 and *Aspergillus* as the elected species in the response filed March 17, 2006 is acknowledged. Upon reconsideration, all the species recited in claims 7 and 18 will be included for examination. Therefore, claims 7, 8 and 14-18 are examined.

Informalities

The disclosure is objected to because of the following informalities:

2. The specification recites an amino acid sequence of SYGRGG (e.g., at page 11, fourth paragraph) and nucleotide sequences (e.g., page 14, third paragraph) without providing a sequence identifier "SEQ ID NO:". Applicants must comply with the requirements of the sequence rules (37 CFR 1.821-1.825) and provide a paper copy and computer readable form of Sequence Listing containing "all" the sequences. Appropriate correction is required.

Claim Objections

3. Claim 16 is objected to because of the use of the term "wherein the koji mold *Aspergillus oryzae* I-2145 (NF14)". It appears a verb is missing in the recited term. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 7, 8 and 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7, 8 and 14-18 are directed to a method for hydrolyzing protein-containing materials or a method of preparing a protein hydrolysate comprising hydrolyzing a proteinaceous material with a Koji mold belonging to the genus *Aspergillus*, *Rhizopus*, *Mucor*, or *Penicillium*, the proteolytic activity of which is not carbon repressed and wherein the *creA* gene has been mutated such that the gene product thereof is essentially nonfunctional. While the specification describes the *creA* gene can be specifically modified such that a non-functional gene product can be obtained and would not block the transcription of protease, and a *creA* mutation may be combined with an increased production of the *areA* gene, a positive stimulator for the production of protease (pages 4-5), the specification does not disclose a method for hydrolyzing protein-containing materials by contacting a proteinaceous material with a Koji mold having a modified *creA* gene, nor indicates a protein hydrolysate produced by the method. Furthermore, the specification does not disclose the use of *creA* mutant in combination with an enzyme or microorganism having a prolidase activity, or the use of a functional derivative of *areA* gene in the claimed method. The specification merely shows the isolation of *creA* mutant, isolation of the *creA* gene, modification of the *creA* gene, and test for mutation of *creA* gene (Examples 1-5), there is no example indicating the claimed methods using the mutated *creA* gene. The lack of description of the method steps for the claimed methods as encompassed by the claims,

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applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

5. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel strain of *Aspergillus oryzae* I-2165 (NF14) to obtain a specific product. The specification discloses at page 10 that NF14 is a *creA* mutant, however, the written description of that strain and the method of isolating are insufficiently reproducible. Therefore, a deposit for patent purposes is required.

For compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. MPEP 2403.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

When the deposit information is disclosed in the specification, the record must also contain a statement certifying that all restrictions on accessibility to said deposit be irrevocably removed by Applicant upon the granting of the patent (see M.P.E.P. § 2404.01); this statement may be certified by Applicants or Applicants' representative.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7-8 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 7-8 and 14-17 are indefinite because the claims lack essential steps in the method for hydrolyzing protein-containing materials. The omitted steps are the step of contacting the protein-containing materials with a koji mold and the outcome of the process. Claims 8 and 14-17 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

78. Claims 7 and 18 recite the limitation "the creA gene" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim. Claims 8 and 14-17 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

9. Claim 17 recites the limitation "the areA gene" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 17 is also indefinite as to "a functional derivative", it is not clear how different the functional derivative is from the parent area gene.

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Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CHIH-MIN KAM
PATENT EXAMINER

CMK

April 13, 2006